Date of preparation:September 22, 2011

FEB - 6 2012

SECTION 5 - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

NAVIAID™ ICVI DEVICE

510(k) Number K 112106

Applicant's Name:

Company name:	Smart Medical Systems Ltd.
Address:	10 Hayetsira Str. Ra'anana 43663 ISRAEL
Tel.:	+972-9-7444321
Fax:	+972-9-7444543
e-mail:	ayoselzon@smartmedsys.com

Contact Person:

Official Correspondent:	Adva Yoselzon
Company name:	Smart Medical Systems Ltd.
Address:	10 Hayetsira Str. Ra'anana 43663 ISRAEL
Tel.:	+972-9-7444321
Fax:	+972-9-7444543
e-mail:	ayoselzon@smartmedsys.com

Name of the device:

NaviAid™ ICVI device

Trade or proprietary name, if applicable:

NaviAid™ ICVI device

Common or usual name:

NaviAid™ ICVI Device

Establishment Registration No.:

3005261802

Classification Name:

Endoscope and accessories

Classification:

FDA has classified Endoscope and accessories devices as a Class II medical device, with product code ODC and 21 CFR classification code 876.1500. Review by the Gastroenterology/Urology Devices Panel.

Predicate Device:

The modified NaviAid™ ICVI device is substantially equivalent to the NaviAid™ ICVI device (manufactured by Smart Medical Systems Ltd. and the subject of 510(k) document no. K110291). A comparison table and detailed discussion are presented in Section 12 of this application.

Device Description:

The modified NaviAid™ ICVI is an on-demand disposable that is inserted through the instrument channel of the endoscope in order to enable advancement and positioning of a standard endoscope in the small intestine. The modified NaviAid™ ICVI Device comprises a disposable balloon system and an air supply control unit for inflating and deflating the balloon system. The role of the ICVI disposable is to facilitate advancement of a standard endoscope into the small intestine. The modified NaviAid™ ICVI disposable includes the ICVI Balloon and the ICVI inflation tube. The balloon is inflated by ambient air. Either the Air Supply Unit ("ASU") or Single Balloon Air Supply Unit ("SB ASU") may operate and control the inflation and deflation of the balloon through a foot-pedal. The balloon is connected to a dedicated inflation tube that runs inside the instrument channel of the endoscope, and is connected at its proximal (user) end to the ASU or SB ASU.

The ICVI balloon can be advanced ahead of the endoscope tip or pulled back through pushing/pulling action on the ICVI inflation tube at its proximal side, outside the patient's body. When the ICVI balloon is advanced and then inflated, it functions as a distal anchor, to which the endoscope tip is advanced, and the ICVI inflation tube serves as a rail that leads the endoscope as it is pushed towards the anchoring ICVI balloon.

The balloon and tube negligibly compromise the endoscope's flexibility, or its field of view. Additionally, the ICVI disposable negligibly compromise the maneuverability of the endoscope's tip and does not limit the usage of any standard endoscopy tools, such as biopsy forceps, snare, needle etc. The ICVI disposable can be pulled back at any time during the procedure in order to allow use of therapy tools.

The NaviAid™ ICVI disposable is intended for single use, while the ASU and SB ASU are re-usable.

Intended Use / Indication for Use:

The NaviAid™ ICVI device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope in the small intestine (i.e., an endoscope that is used for standard intestinal endoscopic visualization and has a compatible instrument channel as defined in the instructions for use)

Comparison of Technological Characteristics with the predicate device:

The modified NaviAid™ ICVI device is similar to the NaviAid™ ICVI device (also manufactured by Smart Medical Systems Ltd. and the subject of 510(k) number K110291) regarding the intended use, technological characteristics, principle of operation, specifications, and safety requirements.

Both the NaviAid™ ICVI device and the modified NaviAid™ ICVI device are intended to facilitate penetration of standard endoscopes into the small intestine, while maintaining all the advantages of an endoscopic procedure, such as back-and-forth navigation, stopping propagation if needed, real-time operation, video imaging, instrument channel including biopsy and treatment. The ICVI disposable can be pulled back at any time during the procedure in order to allow use of therapy tools.

Both devices have the same basic technology and principle of operation, the utilization of a single balloon added to an endoscopy system that is alternately inflated and deflated in order to progress the endoscope and ensure positioning of the endoscope in the small intestine. Both devices are inserted on-demand through the instrument channel of the endoscope.

The NaviAid™ ICVI device includes 3 models (ICVI-F, ICVI-S and ICVI-B) that are compatible for different anatomies of the intestine. These 3 models are compatible with a 3.7mm instrument channel diameter. The modified ICVI Device includes an additional

model, the ICVI-R. The balloon of the ICVI-R may be rotated to fit a 3.2mm instrument channel diameter.

Balloon specifications of all models are the same.

The working length of the modified ICVI is slightly different; the working length of the NaviAid™ ICVI is 3000mm whereas the working length of the modified ICVI is 3500mm. The modified NaviAid™ ICVI device also includes an irrigation cap.

Both devices are supplied non-sterile, for single use only.

The NaviAid™ ICVI Tip is made out of PU whereas the Tip of the modified NaviAid™ ICVI is made out of either the same PU or Pebax as an alternative material. All other patient contact materials are the same.

Both the NaviAid™ ICVI and the modified NaviAid™ ICVI may be controlled by either the Air Supply Unit ("ASU") or Single Balloon Air Supply Unit ("SB ASU").

The ASU is identical between the NaviAid™ ICVI and the modified NaviAid™ ICVI.

The set point pressure tolerance of the SB ASU included in the modified NaviAid™ ICVI device is slightly different.

All other components and parameters are the same with no change in function or user interface.

Both the ASU and SB ASU that control the inflation and deflation of the balloons comply with the electrical and mechanical safety testing requirements and the electromagnetic compatibility testing requirements for electronic medical devices.

Detailed comparison between the NaviAid™ ICVI device and the modified NaviAid™ ICVI device is provided in section12 of this application

Non-Clinical Performance Data

The performance tests include testing of the modified NaviAid™ ICVI Device.

The ASU of the modified NavAid™ ICVI is the same as the ASU of the NaviAid™ ICVI device and the NaviAid™ BGE (also manufactured by Smart Medical Systems), therefore performance tests for the ASU are described in detail in 510(k) number K060923 of the NaviAid™ BGE device.

The SB ASU of the NaviAid™ ICVI is similar to the SB ASU of the modified NaviAid™ ICVI device. The difference between them is the set point pressure tolerance. The set point pressure test is detailed in the performance testing summary. All other tests

performed for the SB ASU of the NaviAid™ ICVI device are also relevant for the SB ASU of the modified NaviAid™ ICVI device and are described in detail in 510(k) number K110291 of the NaviAid™ ICVI device.
The performance testing of the NaviAid™ ICVI disposable are described in 510(k) number K101191 of the NaviAid™ ICVI device

The following performance tests were conducted on the modified NaviAid™ ICVI device:

1. ICVI-In Vitro Validation
2. PU Balloon
3. AB Tip
4. Irrigation Cap
5. AB Compatibility with 3.2mm Working Channel using a Handle
6. ICVI Tube Length
7. Set Point Pressure Tolerance
8. Inflation/Deflation Cycles

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The non-clinical tests demonstrated that the modified NaviAid™ ICVI device meets its design and performance specifications. Furthermore, the tests showed that the modified NaviAid™ ICVI device is easy to use and user friendly and does not cause damage to the intestine or to the endoscope.
The modified NaviAid™ ICVI device may be safely and effectively used in procedures in order to ensure the positioning of a standard endoscope in endoscopy of the small intestine and reach depths of the intestine that may not otherwise be accessible with a standard endoscope device.

Substantial Equivalence:

In summary, the modified NaviAid™ ICVI device is a direct derivative of the NaviAid™ ICVI device. The intended use, basic technology, principle of operation specifications and safety requirements are similar. The minor difference do not raise new questions of safety and effectiveness.

Consequently, the modified NaviAid™ ICVI device is substantially equivalent to the NaviAid™ ICVI device.

Performance Standards:

The NaviAid™ ICVI device complies with the voluntary recognized standards:

1. Electrical & Mechanical Safety Testing (IEC 60601-1)
2. Electromagnetic Compatibility Testing (IEC 60601-1-2)
3. Software Validation (IEC 60601-1-4 & FDA Guidelines)
4. Biocompatibility Testing (ISO 10993)

Note: For the ASU, performance tests relating to standards 1-3 are described in detail in 510(k) number K060923 of the NaviAid™ BGE device. For the SB ASU, performance tests relating to standards 1-3 are described in detail in 510(k) number K110291 of the NaviAid™ ICVI Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Adva Yoselzon
QA Manager and Director of Clinical & Regulatory Affairs
Smart Medical Systems, Ltd.
10 Hayetsira Street
RA'ANANA 43663
ISRAEL

FEB - 6 2012

Re: K112106
Trade/Device Name: NaviAid™ ICVI Device
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: January 18, 2012
Received: January 23, 2012

Dear Ms. Yoselzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112106

Device Name: NaviAid™ ICVI Device

Indications for use:

The NaviAid™ ICVI device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope in the small intestine (i.e., an endoscope that is used for standard intestinal endoscopic visualization and has a compatible instrument channel as defined in the instructions for use)

Prescription Use ___√___ OR Over-The-Counter Use___

(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112106